**Application No.:** 10/509,498

Filing Date: October 27, 2004

## AMENDMENTS TO THE CLAIMS

1. (Currently amended) An vaccine immunogenic composition suitable for administration to a vertebrate host which comprises:

- (a) a polynucleotide vaccine-immunogenic component comprising at least one polynucleotide encoding at least one antigen, such that introduction of said polynucleotide vaccine-immunogenic component into said vertebrate host results in expression of a biologically effective amount of said antigen or antigens so as to induce a prophylactic or therapeutic immune response;
- (b) a protein antigen vaccine immunogenic component comprising at least one protein antigen selected from the group consisting of model protein antigens and vaccine immunogenic protein antigens; and
- (c) a mineral-based, negatively charged adjuvant, wherein said composition produced by a method comprising preincubating or subsequently mixing said mineral-based negatively charged adjuvant is preincubated or subsequently mixed with said at least one protein antigen vaccine—immunogenic component prior to formulating with said polynucleotide vaccine—immunogenic component.
- 2. (Currently amended) The vaccine immunogenic composition according to claim 1 wherein said mineral-based negatively charged adjuvant is an aluminum salt or a calcium salt.
- 3. (Currently amended) The vaccine immunogenic composition according to claim 2 wherein said aluminum or calcium salt is selected from the group consisting of aluminum phosphate, aluminum hydroxyphosphate, phosphate-treated aluminum hydroxide, calcium phosphate, calcium hydroxyphosphate, and phosphate-treated calcium hydroxide.
- 4. (Currently amended) The vaccine immunogenic composition according to claim 1 wherein said group of model protein antigens range from acidic isoelectric point (IEP) proteins to alkaline IEP proteins.
- 5. (Currently amended) The vaccine-immunogenic composition according to claim 1 wherein said group of vaccine-immunogenic protein antigens comprises—is selected from the group consisting of a surface protein or a core protein of Hepatitis B virus (HBV), a de-toxified toxin from the bacteria *Clostridium tetani* (a tetanus toxoid), a de-toxified toxin from the bacteria

**Application No.:** 10/509,498

Filing Date: October 27, 2004

Clostridium botulinus (a botulinus toxoid), and/or a de-toxified toxin from the bacteria Corynebacterium diphtheriae (a diphtheria toxoid).

- 6. (Currently amended) The vaccine-immunogenic composition according to claim 1 wherein said group of vaccine-immunogenic protein antigens comprises protein antigens derived from inactivated poliovirus.
  - 7. (Canceled)
- 8. (Currently amended) A kit comprising an vaccine-immunogenic composition as defined in claim 1 in a unit dose form for administration to a vertebrate recipient.
- 9. (Currently amended) A method of using preincubating or subsequently mixing a mineral-based, negatively charged adjuvant as a component in a combined DNA/protein-based vaccine—immunogenic composition as defined in claim 1, comprising preincubating or subsequently mixing the mineral-based, negatively charged adjuvant with said at least one protein antigen vaccine—immunogenic component prior to being formulated with said polynucleotide vaccine-immunogenic component.
- 10. (Currently amended) An vaccine immunogenic composition suitable for administration to a human host which comprises:
  - (a) a polynucleotide vaccine immunogenic component comprising at least one polynucleotide encoding at least one antigen, such that introduction of said formulation polynucleotide immunogenic component into said vertebrate—human host results in expression of a biologically effective amount of said antigen or antigens so as to induce a prophylactic or therapeutic immune response;
  - (b) a protein antigen vaccine immunogenic component comprising at least one protein antigen selected from the group consisting of model protein antigens and vaccine immunogenic protein antigens; and
  - (c) a mineral-based, negatively charged adjuvant, wherein said mineral-based negatively charged adjuvant is preincubated or subsequently mixed with said at least one protein antigen vaccine-immunogenic component prior to formulating with said polynucleotide vaccineimmunogenic component.
- 11. (Currently amended) A kit comprising an <u>vaccine immunogenic</u> composition as defined in claim 1 in a unit dose form for administration to a human recipient.

**Application No.: 10/509,498** 

Filing Date: October 27, 2004

12. (Currently amended) A method for preparing athe vaccine immunogenic composition according to claim 1, wherein a mineral-based negatively charged adjuvant is preincubated or subsequently mixed with at least one protein antigen vaccine immunogenic component prior to formulating with a polynucleotide vaccine immunogenic component.